

1 **UNITED STATES DISTRICT COURT**
2 **FOR THE DISTRICT OF NEW JERSEY**

3 _____
 CIVIL ACTION NUMBER:

4 **IN RE: VALSARTAN PRODUCTS** **19-md-02875**
5 **LIABILITY LITIGATION**

DISCOVERY CONFERENCE VIA
6 _____
 ZOOM

7 Mitchell H. Cohen Building & U.S. Courthouse
8 4th & Cooper Streets
 Camden, New Jersey 08101
9 October 25, 2023
 Commencing at 10:14 a.m.

10 **B E F O R E:** **THE HONORABLE THOMAS I. VANASKIE (RET.)**
11 **SPECIAL MASTER**

12 **A P P E A R A N C E S:**

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23 Proceedings recorded by mechanical stenography; transcript
24 produced by computer-aided transcription.
25

1 **ALSO PRESENT:**

2 LORETTA SMITH, ESQUIRE
3 Judicial Law Clerk to The Honorable Robert B. Kugler

4 Larry MacStravic, Courtroom Deputy
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1 (PROCEEDINGS held via Zoom before SPECIAL MASTER
2 THOMAS I. VANASKIE at 10:14 a.m.)

3 SPECIAL MASTER VANASKIE: Have we admitted everybody
4 who needs to be admitted, Larry?

5 THE DEPUTY CLERK: Everybody who's in the waiting
6 room is in.

7 SPECIAL MASTER VANASKIE: All right. We're all set
8 to go in.

9 Good morning, everyone. We had a little delay for a
10 fire drill at the courthouse in Camden. But it was just a
11 drill, and that's the good news. And Ann Marie is back now.
12 We're ready to get started.

13 We're going to hear argument today only on -- we call
14 it the motion to seal, but it's really a motion to file in
15 redacted form the expert witness report of Mr. Xue.

16 Am I pronouncing that correctly?

17 MR. COX: I've heard it pronounced different ways,
18 Your Honor. I've heard it pronounced the way you just said
19 and also Xue.

20 SPECIAL MASTER VANASKIE: Xue. All right. We'll go
21 with Xue. It's spelled X-U-E.

22 And you'll be presenting argument, Mr. Cox, on behalf
23 of ZHP on this matter?

24 MR. COX: I will, Your Honor.

25 SPECIAL MASTER VANASKIE: And Mr. Geddis, are you

1 arguing on behalf of the plaintiffs?

2 MR. GEDDIS: Yes, Your Honor.

3 SPECIAL MASTER VANASKIE: All right. I'd like to
4 start off by saying, you know, I looked at the -- obviously
5 looked at the report, and I have the pages for which there are
6 redactions in front of me.

7 There was one ambiguity in the submission, maybe two,
8 but one that I'm looking at. I couldn't tell whether this was
9 part of the redactions sought by ZHP. It's page 11. And it's
10 a little bit ambiguous in terms of there's highlighting on
11 that page. And what you sent to me to assist me in my review
12 was the report with highlights to indicate what's being
13 redacted. But this is not a page that is listed as being at
14 issue with respect to this motion.

15 So can you clarify that, Mr. Cox?

16 MR. COX: Absolutely, Your Honor.

17 And I think because there was some color in the
18 expert report originally, we were -- we ran out of color
19 options in terms of what we could highlight in.

20 SPECIAL MASTER VANASKIE: Right.

21 MR. COX: But I can confirm, page 11, there's nothing
22 that we're asking to be redacted on page 11.

23 SPECIAL MASTER VANASKIE: All right. I suspected
24 that to be the case but just wanted to make sure.

25 All right. So if I was -- do you think it would be

1 appropriate to go page by page here in terms of what you're
2 seeking to redact? And we can certainly seal the transcript
3 if we need to. But it seems to me it might assist me -- I'm
4 trying to understand what the rationale is and what the harm
5 would be to ZHP from having some of this information not
6 redacted.

7 And so, for example, if I went to page 16 of the
8 report, what's redacted there are temperatures.

9 MR. COX: Right, Your Honor.

10 SPECIAL MASTER VANASKIE: And what's the harm from --
11 how does it differ from the information that appears in the
12 patent, which is publicly available?

13 MR. COX: Sure, Your Honor.

14 So the information in the patent is different than
15 the information that's in this report in terms of level of
16 detail, in terms of it having been maintained by the company
17 as confidential. And as Jucai Ge's declaration, it makes
18 clear this information relates to the company's internal
19 processes, manufacturing processes, other processes, very
20 detailed information, including, you know, temperature values,
21 including how many liters or kilograms of specific materials
22 are used in particular steps of a multi-step process.

23 And as she makes clear, other companies, other
24 competitors in the generic pharmaceutical manufacturing space,
25 could use ZHP's processes, the details of those processes, to

1 improve their own processes. They may indicate ways in which
2 those processes could be carried out that they hadn't thought
3 of.

4 And ZHP has spent time and money developing their own
5 processes. The details of them -- and again, the details are
6 not what's in the patents. The patents lay out -- those are
7 the exhibits to Mr. Slater's certification -- lay out in some
8 cases 15 different ways you could do something. And they're
9 all changed a little bit.

10 But what this document shows is how ZHP has done or
11 does a particular process. And that's what ought to be
12 protected, and that's what we're seeking to redact.

13 SPECIAL MASTER VANASKIE: Can I interrupt you for a
14 second and ask --

15 MR. COX: Of course, Your Honor.

16 SPECIAL MASTER VANASKIE: -- Mr. Geddis.

17 I looked at the patent, and the patent seems to
18 provide a range of temperatures, for example, as opposed to a
19 precise temperature that you see in the report.

20 Is that a significant distinction?

21 MR. GEDDIS: Your Honor, thank you.

22 I don't think it is a significant distinction,
23 especially in this context where we have the strong
24 presumption in favor of the public access to court records.
25 And the fact that the patent has a range and ZHP is simply

1 seeking to somehow redact or keep private a number within that
2 range, the patent is public. All the numbers in that range
3 should be protected. And any de minimis interest it has in
4 that specific number, especially -- and I think this is
5 important to remember, that everything in this report is about
6 prior processes before the drug was recalled and before the
7 process was subsequently changed and then actually subject to
8 an additional patent.

9 So I don't think that there's any way for, you know,
10 this conclusory declaration from someone who no longer works
11 at ZHP anymore to overcome the public's right to access this
12 full report, which is central to ZHP's defense in this case.

13 SPECIAL MASTER VANASKIE: You don't dispute that
14 Ms. Ge --

15 Ann Marie, it's spelled J-U-C-A-I, and G-E is the
16 second name or last name.

17 -- that she would have knowledge. I mean, she's been
18 deposed a couple of times. She certainly is knowledgeable.
19 The fact that she no longer works for that particular entity
20 wouldn't destroy her knowledge.

21 MR. GEDDIS: It would destroy her ability to have
22 current personal knowledge about the ability of that
23 information to harm ZHP at this time, which is what ZHP has to
24 prove right now.

25 So just the fact that she knew about what was going

1 on at ZHP before the recall and testified as a 30(b)(6)
2 witness who did indeed have any personal knowledge and to a
3 more limited extent as a fact witness about facts that
4 happened over five years ago doesn't mean that she would have
5 a basis to opine on whether or not this information should be
6 sealed right now. I don't think she does.

7 MR. COX: Your Honor --

8 SPECIAL MASTER VANASKIE: Do you want to respond to
9 that, Mr. Cox?

10 MR. COX: Yes, I do.

11 We disagree with that. And as Your Honor said, I
12 mean, she's been a witness in this case as recently as May
13 2022. She was the quality affairs director of API. She was
14 directly involved with the issues that are implicated by the
15 Xue report. And she -- what she's saying is that the proposed
16 redactions could be used to ZHP's disadvantage. It doesn't
17 matter -- and we cited the UD -- sorry, the UDVNA case, the
18 vodka case. It doesn't matter if the formulas are current or
19 older formulas, the issue is whether they could bring harm to
20 ZHP. And it's still a zinc chloride process that's used, as
21 Mr. Geddis pointed out. There have been changes to that
22 process, but that doesn't alter the fact that how the process
23 has been used over time at ZHP at its expense, at its cost,
24 could be unfairly leveraged by its competitors in the generic
25 marketplace.

1 SPECIAL MASTER VANASKIE: Thank you.

2 Now, on pages 23 and 26, 27, 28, 29 -- sorry -- of
3 the Xue report, there are tables there, Table 1a-2 captioned
4 "Main Materials Charging and Production Capacity Comparison."

5 Now, why is it important to ZHP that the information
6 that's redacted is not the entire table that's redacted, it's
7 only certain information? Why is it important that that
8 information be redacted?

9 MR. COX: Right. And that goes to ZHP making an
10 effort here to use the least restrictive means. You can see
11 that we're not trying to redact the step involved or the
12 original process, but it's the proposed process and the
13 reasoning in that far right-hand column, that note on the
14 changes that would reveal to ZHP's competitors why it's making
15 particular changes, what it thinks about certain processes
16 that are part of its manufacturing process. And that is
17 insight that a competitor could use to its advantage and to
18 ZHP's disadvantage, because essentially by making the document
19 public, ZHP's competitors would have access to information
20 that they do not have access to right now and could use to
21 improve or change their own processes.

22 SPECIAL MASTER VANASKIE: Mr. Geddis, what Mr. Cox is
23 saying seems to make sense to me, that, you know, the fact
24 that ZHP is a defendant in this case doesn't open up an
25 examination of proposed processes.

1 Why should -- and why should not that information at
2 least be protected?

3 MR. GEDDIS: The problem, Your Honor, is that this
4 information is in the expert report, where ZHP tries to
5 exonerate itself from liability in this case. It's its
6 primary defense in this entire litigation. And the Court has
7 already recently certified the class action, and we're going
8 to be going to trial. This report is going to be subject to
9 further motions, attached to further motions. And the public
10 and absent class members have a right to understand why ZHP
11 thinks that it did nothing wrong in this case and it had no
12 basis to understand the basic chemistry underlying the
13 formation of NDMA in its valsartan.

14 And if you look at the information on page 23, this
15 is a primary example of how this motion is not in any way
16 following the least restrictive approach, because you see the
17 first three rows that they're trying to redact, there is no
18 change. So how can this possibly need to be redacted?

19 Then if you go to this second cutout, where the, you
20 know -- just second gray bar in this chart, they're seeking to
21 redact the fact that they use zinc chloride after they use
22 triethylene. That is the most widely known fact in this
23 litigation. It's the name of the process that we talk about
24 nonstop. Why does that need to be redacted?

25 And just above that, they're seeking to redact the

1 fact that they use DMF in the second process. That's the
2 chemical that introduced DME -- or excuse me, DMA that led to
3 the formation of NDMA in this case.

4 Just those few examples show you that even besides
5 the fact that Jucai Ge doesn't have personal knowledge at this
6 point to opine on whether or not this information could be
7 prejudicial to ZHP, she didn't look at the charts carefully.
8 And she didn't even seek to address our arguments that were
9 repeated over and over again, that the patents precluded any
10 prejudice to ZHP.

11 And if they wanted to be able to come here and tell
12 you that the patents aren't enough protection, they should
13 have shown them to her and had her say, I looked at the
14 patents, here's why they don't protect ZHP at this point.

15 It's -- the declaration is completely conclusory.
16 And she often doesn't address any of the info -- or much of
17 the information with the requisite specificity.

18 So I think the Court needs to deny the motion to seal
19 and allow the public and absent class members to assess ZHP's
20 proffered defense in this case.

21 SPECIAL MASTER VANASKIE: Mr. Geddis, what would you
22 propose would be the specificity that should have been in this
23 declaration that's missing?

24 MR. GEDDIS: Like I said, Your Honor, I think she
25 should have at least had the patent, explained that she

1 reviewed the patents, compared the patents to the information
2 that she was seeking to redact, and explain why that was
3 not -- that those patents didn't provide enough protection for
4 them.

5 SPECIAL MASTER VANASKIE: What has precluded you from
6 presenting your own declaration to that effect?

7 MR. GEDDIS: We don't have the burden of proof here.
8 And I think as you explained, Your Honor, the patents are
9 public. And they have -- as I outlined in a lot of detail on
10 pages 13 and 14 of my brief, most of the chemicals that
11 they're seeking to redact are described in the patents, in all
12 three of them.

13 So I think given the public's right -- strong
14 presumption of the public's right to access these court
15 records, and the fact that these patents provide -- one, they
16 provide a significant amount of protection to ZHP; two, they
17 outline much of the information they're seeking to redact, I
18 don't see how there's any way for ZHP to claim that there's
19 any risk of harm that would outweigh the public right to
20 access these documents.

21 I mean, the same outcome was reached in *Avandia*,
22 where the court completely unsealed, you know, half a dozen
23 expert reports and declarations, and explained, quote: In
24 this long-running MDL, implicating the public's trust in a
25 well-known and formerly widely used drug, the interests the

1 common law is meant to protect are particularly important, 484
2 F. Supp. 3d 249.

3 SPECIAL MASTER VANASKIE: I understand all of that.
4 I've been down this road before in the case.

5 But it seems to me that ZHP is at least attempting
6 here to use the least restrictive means to protect valuable
7 proprietary information. They're not seeking to redact the
8 entire report, they're only seeking to redact -- for example,
9 on the tables that appear on pages 23, 26, 27 and 28 -- I'm
10 sorry, my fingers are not working the -- and 29, they're only
11 seeking to redact information concerning what happened after
12 changes were made. And that seems to me to be the kind of
13 information that would be valuable to a competitor.

14 Why shouldn't that get protected?

15 MR. GEDDIS: Well, I think -- I don't know -- I just
16 want to clarify that this is not after the changes after the
17 recall. This is a change from the first or -- the first
18 contaminating process that was instituted in 2012
19 approximately and then they changed it to the zinc chloride
20 process in -- later in 2012 or early 2013, and they used that
21 process that's discussed in this report up until the recall.
22 And all this information that you see, these photos and
23 everything, comes from their response to the FDA's inspection
24 in July and August of 2018.

25 And this is their explanation of why they went from

1 the TEA process to the zinc chloride process. And at this
2 time it was really only known that the zinc chloride process
3 created NDMA. And so that's why they were focused on, why did
4 we go from TEA that didn't seem to create this problem to zinc
5 chloride where there was this massive amount of carcinogenic
6 NDMA in the product.

7 And that's -- that's why -- I just want to make sure
8 that the Court is clear that this change is before the recall
9 and that's why it's essentially the heart of this case. And
10 this entire report is about the heart of this case. And the
11 public has a right to understand how its drug supply became
12 contaminated with NDMA. And absent class members, who are
13 soon going to be asked to decide whether or not to bind
14 themselves to the rest of this Court's proceedings, also have
15 a strong interest in deciding what's going on with this case
16 and why ZHP thinks it did nothing wrong.

17 MR. COX: Your Honor, can I address that point?

18 SPECIAL MASTER VANASKIE: Yes, Mr. Cox. Go ahead.

19 MR. COX: Thank you.

20 In terms of the public and the presumption of the
21 public right to access, I mean, the public has abundant
22 materials available to them to evaluate the merits of these
23 allegations. I mean, there are pleadings. There is briefing.
24 There are eight other defense expert reports. There are
25 plaintiffs' experts reports. There's Dr. Xue's opinions, as

1 you pointed out. We're asking for only a small portion of
2 this report to be redacted. There are testing documents that
3 have been filed. There are FDA materials that are publicly
4 available that have been filed in this case. The proposed
5 redactions -- and we paid attention to this. The proposed
6 redactions do not show whether or not, you know, there are
7 nitrosamines in the product.

8 And the court in the *Supernus v. TWI Pharmacies* case,
9 you know, captured this point I think really well. There the
10 court said: The confidential information here -- the specific
11 formulation of TWI's ANDA products -- has extremely limited
12 public utility. This information is useful only to those
13 businesses that would seek to benefit, to TWI's detriment, in
14 the highly competitive generic pharmaceutical marketplace.

15 I mean, these redactions, as Your Honor has already
16 pointed out today, you know, concern how much, how many
17 liters, you know, how many kilograms, what temperature were
18 used in a pharmaceutical manufacturing step. And that
19 information, you know, isn't actionable by the public, but it
20 is by ZHP's competitors. And that would be the result of
21 disclosure of this information.

22 MR. GEDDIS: Your Honor, I think the problem is --

23 SPECIAL MASTER VANASKIE: Yes, go ahead. Go ahead.

24 MR. GEDDIS: The problem is that all the other
25 information about this case and about what went on here says

1 that ZHP should have known about this contamination as soon as
2 it started developing the process. And this is -- this is the
3 one document that purports to show that it shouldn't have
4 understood that problem. So everyone -- if they're going to
5 understand what's going on here and why ZHP thinks it did
6 nothing wrong, they need to know what's in this report.

7 And as explained in my -- in the brief, ZHP has a
8 history of obfuscating documents that have been partially
9 unsealed in this case and saying, well, you don't really
10 understand what happened because you don't speak Chinese or
11 you don't know what the full email has to say.

12 This is an expert report that's supposedly laser
13 focused, according to their briefing, only on rebutting our
14 experts, which is obviously not true as we explained in our
15 Daubert briefing. But it's absolutely focused on showing that
16 ZHP did nothing wrong in this case. So I don't know how they
17 can claim that information in this expert report is irrelevant
18 to understanding why they did everything right.

19 SPECIAL MASTER VANASKIE: I don't think the argument
20 is that it's irrelevant. Obviously it's out there. It's part
21 of the report. It will be subject to examination at the time
22 of trial.

23 The only issue is should it be in the public realm.
24 And I'm not hearing from you why -- and absent -- or not an
25 absent. Why a class member, a putative class member would

1 need to know the type of details that you see in these charts,
2 for example, to evaluate whether to stay as a class member or
3 not.

4 MR. GEDDIS: Well, it's because -- their argument,
5 Your Honor, is that they made all of these changes and that
6 they did a very thorough job in allegedly assessing the change
7 that resulted in the contamination, and because they did such
8 a thorough job, that it should be ignored that the NDMA was
9 created in the process.

10 And so the public and the absent class members need
11 to understand what is this incredibly thorough job that you're
12 claiming you did in developing this zinc chloride process, and
13 as a result, I guess we should just overlook the fact that it
14 created NDMA.

15 MR. COX: No one is asking that the conclusions be
16 overlooked. As Your Honor said, what we're asking is that the
17 very detailed information that Ms. Ge has submitted a
18 declaration on showing a serious and defined harm that would
19 occur if disclosure occurred ought to be sealed. And that's a
20 mechanism that we have so that a defendant can defend itself
21 but also protect proprietary information at the same time.

22 And that's all we're asking for, Your Honor, is that
23 this not be divulged to the public, which would have the
24 effect of divulging it to ZHP's competitors and result in the
25 harm that Ms. Ge avers to in her declaration.

1 SPECIAL MASTER VANASKIE: I'm looking at the table on
2 page 34, Table 1a-9, "Impurity Evaluation of Condensation
3 Compound Hydrochloride."

4 And the table lists an impurity as a chemical
5 structure, diagram, source, affected by change yes or no, and
6 impact level. And I'm struggling to see why this information
7 needs to be redacted. I don't see -- you can get the chemical
8 compound -- the structure of the impurity from any number of
9 sources, I imagine.

10 Why does this need to be redacted?

11 MR. COX: Your Honor, here -- and I think we address
12 this in our reply brief -- it's, you know, the -- it's the
13 entire presentation, but particularly the affected by change
14 yes or no column and the impact column on the right-hand --
15 the two columns that are on the right-hand side, which again
16 reflects ZHP's, you know, internal thinking, understanding of
17 how these process changes are impacting the impurity
18 evaluation, not disputing that some of the information in the
19 left-hand columns is available, but it's not presented in this
20 entire context with ZHP's thinking, which is on the right --
21 in the two right-hand columns. And you can get to that at the
22 end of the chart, particularly on page 36, where the impact
23 levels change in very tiny writing.

24 SPECIAL MASTER VANASKIE: Very tiny writing.

25 MR. COX: Yeah.

1 SPECIAL MASTER VANASKIE: I have to get my magnifying
2 glass out.

3 MR. COX: That's what I was doing. I guess mine is
4 taking my glasses off.

5 SPECIAL MASTER VANASKIE: I've already done that.

6 Mr. Geddis, any response on that?

7 MR. GEDDIS: I think it's just another example, Your
8 Honor, of how they're not following the least restrictive
9 method.

10 You know, on page 36 again they're redacting zinc
11 chloride, they're redacting DMF, they're redacting toluene.
12 And as explained again on pages 13 and 14 of the brief, there
13 are numerous other chemicals that are listed in this chart
14 that are in the patents, and there's absolutely no basis for
15 redacting them here. And, again, just like Ge does not have
16 current personal knowledge that she can opine that this
17 information should be redacted, the fact that she is opining
18 that this information should be redacted shows she doesn't
19 have personal knowledge that's current. And it undermines the
20 entire declaration.

21 SPECIAL MASTER VANASKIE: I'm not sure about that. I
22 mean, she has been a knowledgeable person, and you don't lose
23 your knowledge simply because you're no longer with the same
24 entity.

25 You wouldn't be making that argument if she still

1 worked there.

2 MR. GEDDIS: But, Your Honor, that's the problem, she
3 doesn't work there.

4 SPECIAL MASTER VANASKIE: But I think she has a basis
5 for knowing how ZHP could be harmed by the public disclosure
6 of this particular type of information.

7 All right. Is there anything else you wanted to
8 present, Mr. Cox?

9 MR. COX: No, Your Honor.

10 Well, I think we -- ZHP has met -- has provided a
11 basis for you to answer the four questions that are relevant
12 here with an affirmative response, which is: Is the nature
13 and substance of the information of the type that requires
14 sealing? Has ZHP shown a serious and defined harm that would
15 ensue from the disclosure? And do the interests of avoiding
16 that harm outweigh the public interest in access? And has ZHP
17 proposed the least restrictive means?

18 I think the answer to all those questions is yes,
19 Your Honor, and for that reason ask you to grant the motion to
20 seal and file a redacted copy of the Xue report.

21 SPECIAL MASTER VANASKIE: Mr. Geddis?

22 MR. GEDDIS: Your Honor, I think I've explained, you
23 know, plaintiffs' position that just like Ge doesn't have the
24 personal knowledge needed to support her declaration, there
25 are countless examples in the briefing and that I've already

1 explained that show that they're not using the least
2 restrictive method and the patents provide the necessary
3 protection that ZHP needs. If they are worried about, you
4 know, minor details within a specific temperature range or
5 things like that, that limited interest cannot over --
6 outweigh -- excuse me, outweigh the public's right to access
7 this information that's found in ZHP's key liability report in
8 this case. And the public has a right to understand why ZHP
9 thinks it did nothing wrong here. And the Court should
10 consequently deny ZHP's motion to seal this report or anything
11 in it.

12 SPECIAL MASTER VANASKIE: Thank you very much.

13 Anything else?

14 MR. COX: No, Your Honor.

15 SPECIAL MASTER VANASKIE: Ann Marie, thank you very
16 much. I'll get the transcript, and we'll issue a decision
17 promptly.

18 Anything else?

19 (No response.)

20 SPECIAL MASTER VANASKIE: You're all going to get
21 back to me, I take it. I know this isn't your motion, but we
22 have the WeChat motion that we were going to hear argument on
23 today. And we're postponing that, so I'll wait to hear from
24 you on that.

25 And we have -- I guess I'll be in Camden next week,

1 because we have a case management conference.

2 Is that right, Loretta?

3 LAW CLERK: Yes, Your Honor.

4 SPECIAL MASTER VANASKIE: Okay.

5 LAW CLERK: Yes. It's on -- I believe it's on
6 Wednesday at 2:00 p.m. in person in the court.

7 SPECIAL MASTER VANASKIE: All right. And I'd like to
8 get a report back from counsel about where you stand with
9 respect to the WeChat motion before we have our conference
10 next Wednesday.

11 All right. Thank you all very much. Take care.

12 (Proceedings concluded at 10:46 a.m.)

13 - - -

14 I certify that the foregoing is a correct transcript
15 from the record of proceedings in the above-entitled matter.

16 /S/ Ann Marie Mitchell 25th day of October, 2023
17 Court Reporter/Transcriber Date

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/	A			
/S [1] - 22:15	a.m [3] - 1:9, 3:2, 22:12	arguments [1] - 11:8 ARPS [1] - 1:16	certainly [2] - 5:2, 7:18	competitors [6] - 5:24, 8:24, 9:14, 9:19, 15:20, 17:24
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